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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/229,229	01/12/99	WAHL	G

HM22/1023
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EXAMINER	
HOLLERAN, A	
ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/229,229	Applicant(s) WAHL ET AL.	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *5-27,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed August 2, 2001 is acknowledged.

Claims 1-32 are pending.

Claims 5-27, 31 and 32, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1-4 and 28-30 are examined on the merits.

Claim Rejections Withdrawn:

2. The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to claim 1.

3. The rejection of claims 1, 3, 4 and 29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,033,849 in view of Snapka et al is withdrawn upon further consideration.

Claim Rejections Maintained:

4. The rejection of claims 28 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record.

This rejection would be overcome if the claims were amended to recited "further comprising" to indicate that the steps recited in claims 28 and 30 were in addition to the method steps of claims 1 and 29.

5. The rejection of claims 1, 3, 28, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over Eckhardt et al (Eckhardt, S.G. et al., Proc. Natl. Acad. Sci. USA, 91: 6674-6678, 1994; cited in the IDS) in view of Snapka et al (Snapka, R.M. et al, Proc. Natl. Acad. Sci., USA 80: 7533-7537, 1983; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments have been considered but are unpersuasive. Applicant argues that neither Eckhardt nor Snapka, alone or in combination, describe or suggest a method for identifying an agent that causes loss of double minute chromosomes or extracellular DNA from a cell through a mechanism involving micronucleation and loss of the DNA. This unpersuasive because Eckhardt teaches a method of determining micronucleation in response to hydroxyurea and teaches that hydroxyurea treatment leads loss of Myc and to differentiation of tumor cells. Applicant further argues that neither Eckhardt nor Snapka, alone or in combination, describe for identifying an agent for treatment of neoplastic cells. This is unpersuasive because Eckhardt provides the teaching of the methodology and Snapka provides the motivation to look for other agents. Snapka teaches that an approach to the problem of cancer cells that overexpress undesirable amplified genes is to look for ways to increase the probability of loss of the amplified genes and reports that cells grown in the presence of hydroxyurea have an increased rate of loss of DHFR genes. Thus, the teachings of Eckhardt and Snapka taken together suggest to one of skill in the art to devise methods such as the claimed methods.

6. The rejection of claims 1, 3, 4, 28, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over Eckhardt et al (Eckhardt, S.G. et al., Proc. Natl. Acad. Sci. USA, 91: 6674-6678, 1994; cited in the IDS) in view of Snapka et al (Snapka, R.M. et al, Proc. Natl. Acad. Sci., USA 80: 7533-7537, 1983; cited in the IDS) and further in view of U.S. Patent 5,858,667 (Dertinger et al) is maintained for the reasons of record.

Applicant's arguments have been considered, but are unpersuasive. The teachings of Dertinger are evidence that methods of micronuclei measurement by flow cytometry are known in the art. Thus, the methods of claim 4 are obvious over the prior art as a whole.

7. The rejection of claims 1,23, 28, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over Eckhardt et al (Eckhardt, S.G. et al., Proc. Natl. Acad. Sci. USA, 91: 6674-6678, 1994; cited in the IDS) in view of Snapka et al (Snapka, R.M. et al, Proc. Natl. Acad. Sci., USA 80: 7533-7537, 1983; cited in the IDS) and further in view of Livingstone et al (Livingstone, L.R. et al., Cell, 70: 923-935, 1992; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments have been considered, but are unpersuasive. The teachings of Livingston are evidence that alterations in the p53 gene leading to lack of a functional tumor suppressor protein may lead to gene amplification and that p53 mutations are present in a variety of cancers. Thus, the methods of claim 2 are obvious over the prior art as a whole.

8. The rejection of claims 1, 3, 4, and 29 under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (Shimizu, N. et al. Nature Genetics, 12: 65-, 1996; cited in the IDS) in view of

Snapka et al (Snapka, R.M. et al, Proc. Natl. Acad. Sci., USA 80: 7533-7537, 1983; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments have been considered, but are unpersuasive. Shimizu teaches both the methodology of the claimed methods and suggests that elimination of double minute chromosomes from tumor cells would provide a chemotherapeutic strategy to target tumor cells. Snapka teaches that an approach to the problem of cancer cells that overexpress undesirable amplified genes is to look for ways to increase the probability of loss of the amplified genes and reports that cells grown in the presence of hydroxyurea have an increased rate of loss of DHFR genes. Thus, the claimed methods are obvious over the teachings of the prior art as a whole.

9. The rejection of claims 1, 3, 4, and 29 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,033,849 in view of Snapka et al (Snapka, R.M. et al, Proc. Natl. Acad. Sci., USA 80: 7533-7537, 1983; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments have been considered, but are unpersuasive. U.S. Patent 6,033,849 teaches both the methodology of the claimed methods and suggests that elimination of double minute chromosomes from tumor cells would provide a chemotherapeutic strategy to target tumor cells (col. 1, line 55- col. 2, line 11). Snapka teaches that an approach to the problem of cancer cells that overexpress undesirable amplified genes is to look for ways to increase the probability of loss of the amplified genes and reports that cells grown in the presence of hydroxyurea have an increased rate of loss of DHFR genes. Thus, the claimed methods are obvious over the teachings of the prior art as a whole.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
October 22, 2001

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